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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,659	05/11/2001	Steven M. Ruben	PZ003P4	5111

22195 7590 05/05/2004

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,659	RUBEN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-35 and 56-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-35 and 56-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/4/03,12/1/03,2/2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Papers filed 31 October 2003, 1 December 2003, 25 January 2004 and 23 February 2004 in response to the Non-Final Office Action mailed 21 October 2003. Claims 24-35 and 56-75 were considered in the 21 October Office Action. No amendments have been made to the claims. Claims 24-35 and 56-75 are presently pending and under consideration.

Inventorship

In view of the papers filed 31 October 2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Gregg A. Hastings as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Information Disclosure Statement

The Information Disclosure Statements filed 4 August 2003, 1 December 2003 and 23 February 2004 have been considered. The references lined through on the 4 August form PTO/SB/08 were made of record on the PTO-892 mailed 21 October 2003.

Response to Arguments

Claims 24-35 and 56-75 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The Examiner's position, as stated in the previous Office Action is that, "the disclosure fails to provide basic and essential guidance as to how one of ordinary skill would be able to use the claimed invention to diagnose or treat preeclampsia, such as whether neurokinin B levels are altered in preeclampsia or whether to administer an agonist or antagonist of neurokinin B to treat preeclampsia. Thus, there is failure to meet the enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art" (page 8).

In response, Applicant alleges that one of skill in the art at the time of filing would have expected an increase in the level of the HPMBQ91 polypeptide of the instant invention to be associated with preeclampsia and indicative of the disorder. Applicant bases this position on teachings in the art that neurokinin B and neurokinin B mimetics can induce general hypertension when administered to the nucleus tractus solitarii of rats (Nagashima *et al.*) and upon intravenous administration in guinea-pig (Roccon *et al.*).

This argument has been fully considered but is not deemed persuasive. At the time of filing the skilled artisan would have known, based on the teachings of the instant specification, only that the claimed polypeptide has structural similarity to a neurokinin B and is expressed in normal placenta. Based on the teachings cited by Applicant the skilled artisan would know that neurokinin B-type agonists induce hypertension when administered systemically to guinea pigs

or directly into a specific portion of the rat brain. However, based on the teachings cited in the previous Office Action the skilled artisan would also know that response of the vasculature to tachykinins is complex, depending upon the animal, species, density in the smooth muscle cells, and the endothelium of the different receptor types as well as the kind of tachykinins administered or released (see, *e.g.,* Severini *et al.* cited on page 5 of the previous Office Action). Furthermore, Roccon *et al.* cites findings indicating that the hypertensive effect of neurokinin B described in guinea pigs may not extend to other mammalian species because the same neurokinin B-type agonists that elicited a hypertensive response from guinea pigs produced a hypotensive response when administered systemically to normotensive rats (Couture *et al.* (1989) *Naunyn Schmiedebergs Arch Pharmacol.* 340:547-557, cited in the first full paragraph on page 1101 of Roccon *et al.*). Roccon *et al.* speculates that these findings suggest a differential functional role for NK_3 receptors in the control of the cardiovascular system in different species (first full paragraph on page 1101).

There is no teaching either in the art at the time of filing or in the instant specification that elevated levels of the claimed protein are in any way associated with preeclampsia, or that administration of a neurokinin B agonist or antagonist would be therapeutic in preeclampsia. Even if one of skill in the art might have expected an increase in the level of the HPMBQ91 polypeptide of the instant invention to be associated with preeclampsia and indicative of the disorder, at the time of filing this would have been no more than a plausible hypothesis because there was no evidence that expression of HPMBQ91 polypeptide was increased under any circumstance. Furthermore, given the different responses to neurokinin B-type agonists seen in different mammalian species, a hypothesis that a decrease in neurokinin B expression would be

associated with preeclampsia and indicative of the disorder would be equally plausible. Thus, the information in the instant specification and available in the art at the time of filing fails to provide basic and essential guidance as to how one of ordinary skill would be able to use the claimed invention to diagnose or treat preeclampsia. Therefore, the disclosure is not enabling for the claimed subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER